

REMARKS

Claims 21 to 46 are pending in the application.

The Examiner required restriction to one of the following groups of claims under 35 U.S.C. § 121:

Group I: Claims 21-33, allegedly drawn to “a method of producing a transgenic mouse comprising a vector comprising a 5’ gene trap cassette and a 3’ gene [trap] cassette by introducing said vector into murine embryonic stem cells, classified in classes 435 and 800, subclasses 320.1 and 21, respectively.” Action at page 2.

Group II: Claims 34-46, allegedly drawn to “a method of producing a transgenic mouse comprising a vector comprising a 3’ gene [trap] cassette by introducing said vector into murine embryonic stem cells, classified in classes 435 and 800, and subclasses 320.1 and 21, respectively.” *Id.*

Applicants elect Group II, with traverse. Applicants traverse the restriction requirement for the reasons provided below.

Applicants assert that the Examiner failed to present a *prima facie* showing of serious burden to search and examine the entire application, as required by § 803 of the Manual of Patent Examining Procedure (MPEP). According to the MPEP, restriction to one of two or more claimed inventions is proper “only if they are . . . either independent . . . or distinct,” and the search and examination of the entire application “must be a serious burden on the examiner.” *Id.* The MPEP further states that “[f]or purposes of the initial requirement, a serious burden on the examiner may be *prima facie* shown if the examiner shows by appropriate explanation of **separate classification**, or **separate status in the art**, or a different field of search as defined in MPEP § 808.02.” *Id.* (emphasis added). Moreover, “[i]f the search and examination of an entire application

can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions.” *Id.*

The Examiner alleged that “Groups I and II are distinct from each other because they are drawn to different scientific considerations: the use of a vector comprising a 5’ gene trap cassette and a 3’ gene trap cassette to make a transgenic mouse vs. the use of a vector comprising only a 3’ gene trap cassette to make a transgenic mouse.”

Action at page 2. The Examiner then alleged that “[t]hey are materially different methods that differ in method steps, reagents used, dosages and schedules used, response variables, and criteria of success.” *Id.* at pages 2 and 3.

Applicants assert that the vectors recited in claims 21 to 33 and 34 to 46 are not drawn to “different scientific considerations,” contrary to the Examiner’s contentions. In fact, the methods for introducing the vectors into ES cells are similar, including the method steps, dosages, and schedules used. Furthermore, the intended result of that introduction is the same for both vectors: disruption of a gene in the genome of a murine embryonic stem cell. One skilled in the art would therefore recognize that the vector recited in claims 21 to 33 may be used for a similar purpose as the vector recited in claims 34 to 46. Thus, those vectors are drawn to similar scientific considerations, and share similar status in the art.

The Examiner further alleged that “[b]ecause these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and **as shown by their different classification**, restriction for examination purposes as indicated is proper.” Action at page 3 (emphasis added). In fact, the Examiner himself indicated that **Group I and Group II are in the**

exact same classes and subclasses. See Action at page 2 (Group I is "classified in classes 435 and 800, subclasses 320.1 and 21, respectively." Group II is "classified in classes 435 and 800, subclasses 320.1 and 21, respectively."). The fact that Group I and Group II are in the same classes and same subclasses only supports applicants' position that the claimed methods have not acquired separate status in the art, nor do they represent "recognized divergent subject matter." To the contrary, the claimed methods have been recognized as *not* being divergent subject matter, as evidenced by their identical classifications. Thus, the claimed methods are not in separate classifications, do not have separate status in the art, and are not in different fields of search, as required by the MPEP for a *prima facie* showing of serious burden. Applicants therefore assert that the Examiner has failed to make a *prima facie* showing of serious burden, and applicants assert that the restriction requirement is improper.

Applicants respectfully request reconsideration and withdrawal of the restriction requirement, and respectfully request that the Examiner search and examine claims 21 to 46 together.

Please grant any extensions of time required to enter this Response and charge any additional required fees to Deposit Account No. 06-0916.

Respectfully submitted,

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By: _____



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